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ORIGINAL ARTICLE

Contrast-enhanced swallow study sensitivity for anastomotic leak detection in post-esophagectomy patients☆

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Estudio contrastado;
Sensibilidad diagnóstica

Abstract
Introduction and aims: Esophagectomy is a highly invasive surgery and one of its postoperative complications is anastomotic leakage, occurring in 53% of cases. The aim of the present study was to determine the sensitivity of the contrast-enhanced swallow study as a method for diagnosing anastomotic leak in patients that underwent esophagectomy.
Materials and methods: The present retrospective study included the case records of patients that underwent esophagectomy with reconstruction and cervical anastomosis at the *Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán* within the time frame of January 1, 2000 and May 31, 2016. Demographic, clinical, and laboratory data emphasizing clinical and radiographic anastomotic leak detection were identified. Descriptive statistics were carried out and contrast-enhanced swallow study sensitivity for diagnosing leakage was calculated.
Results: Seventy patients were included in the analysis. The mean age of the patients was 50.6 years, 51 of the patients were men (72.86%), and 19 were women (27.14%). Indications for surgery were benign lesion in 29 patients (41.4%) and malignant lesion in 41 (58.6%). A total of 44.3% of the patients presented with a comorbidity, with diabetes mellitus and high blood pressure standing out. Thirty patients (42.85%) presented with anastomotic leak. Contrast-enhanced swallow study sensitivity for leak detection was 43.33%.

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Conclusions: The diagnostic sensitivity of the contrast-enhanced swallow study was very low. Therefore, we recommend the discontinuation of its routine use as a method for diagnosing anastomotic leaks.

Sensibilidad del estudio contrastado para la detección de fuga de la anastomosis en pacientes post-esofagectomía

Resumen
Introducción y objetivo: La esofagectomía es una cirugía altamente invasiva, y una de sus complicaciones postoperatorias es la fuga anastomótica, que ocurre hasta en el 53% de los casos.El objetivo de este trabajo es conocer la sensibilidad del estudio contrastado como método diagnóstico de fuga anastomótica en pacientes a los que se les realizó esofagectomía.
Material y métodos: Estudio retrospectivo donde se incluyeron los expedientes clínicos de pacientes a los que se les realizó esofagectomía con reconstrucción y anastomosis cervical en el Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán en el período entre el 1 de enero de 2000 y el 31 de mayo de 2016. Se identificaron factores demográficos, clínicos de laboratorio, con énfasis en la detección de fugas de anastomosis por clínica y radiología.Se realizó estadística descriptiva y se calculó la sensibilidad del estudio contrastado para el diagnóstico de fuga.
Resultados: Se incluyeron 70 pacientes. La edad promedio fue 50.6 años, y eran 51 hombres (72.86%) y 19 mujeres (27.14%). En 29 pacientes (41.4%) la indicación quirúrgica fue la de lesiones benignas, mientras que en 41 pacientes (58.6%) la indicación fue una neoplasia maligna. El 44.3% presentaron algún tipo de comorbilidad, entre las que destacaron diabetes mellitus e hipertensión arterial. La fuga en la anastomosis se presentó en 30 pacientes (42.85%). La sensibilidad del estudio contrastado para la detección de fugas fue del 43.33%.
Conclusiones: La sensibilidad diagnóstica del estudio contrastado fue muy baja, por lo que recomendamos abandonar su uso rutinario como método diagnóstico de fugas anastomóticas.

Introduction and aims

Esophagectomy is a highly invasive surgery. Its main indication is for cancer and it is associated with high morbidity and mortality. One of the most dreaded postoperative complications is anastomotic leakage, which occurs in up to 53% of cases.[1] According to the United Kingdom Surgical Infection Study Group, anastomotic leakage is defined as ''the leak of luminal content from a surgical join between two hollow viscera''. Luminal content can leak through the wound or at the drainage site or form collections near the anastomosis, causing fever, perianastomotic collections (hematomas, seromas, or abscesses), sepsis, mediastinitis, empyema, pneumothorax, metabolic stress and/or multiple organ failure. The escape of luminal content from the site of the anastomosis into an adjacent area, with no signs or symptoms, and detected through imaging study, is considered a subclinical leak.[2–4]

Detection and early treatment of anastomotic leaks is essential for reducing morbidity. Many hospitals currently perform routine contrast-enhanced swallow study at the first postoperative week to detect subclinical anastomotic leaks. The contrast-enhanced study's low sensitivity has been reported and the gold standard for anastomotic leak detection has yet to be established.

The aim of the present study was to know the sensitivity of the contrast-enhanced swallow study as a method of detecting anastomotic leak in patients that underwent esophagectomy.

Materials and methods

The present retrospective study included patients that underwent esophagectomy at the *Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán* within the time frame of January 1, 2000 and May 31, 2016. The information was collected from the case records.

The inclusion criteria were patients that underwent esophagectomy for any indication and whose case records were complete. The exclusion criteria were esophageal surgical techniques that were not esophagectomy and incomplete case records.

The variables studied were age, sex, indication for surgery (benign or malignant disease), comorbidities, clinical stage in the cases of malignant lesions, neoadjuvant therapy, surgical technique, type of reconstruction, complications, surgery duration, blood loss, preoperative and postoperative hemoglobin levels, anastomotic leak, and leak detection through contrast-enhanced swallow study. Said contrast-enhanced study was carried out between 5 and 7 days after surgery with water-soluble material. Anastomotic leak was defined as the leakage of contrast material from the esophageal lumen reported by the radiology service (fig. 1). Clinical anastomotic leak was defined as the leakage of saliva or food through the surgical wound in the neck or the presence of an abscess at said level that required the opening of the surgical wound (fig. 2).

Descriptive statistics were carried out, calculating percentages and means. Contrast-enhanced swallow study sensitivity for anastomotic leak detection was calculated, using the clinical diagnosis of the leak as the gold standard.

Results

Our study group was made up of 70 patients that underwent esophagectomy during the study period. Their mean age was 50.6 years (range: 13 to 81 years), with a median of 52 years. The study group included 51 men (72.86%) and 19 women (27.14%). A total of 44.3% of the patients presented with a comorbidity. Six patients (8.57%) had diabetes mellitus, 8 (11.43%) had high blood pressure, and 8 patients (11.43%) presented with major depression, the majority of whom (6/8) were women (75%).

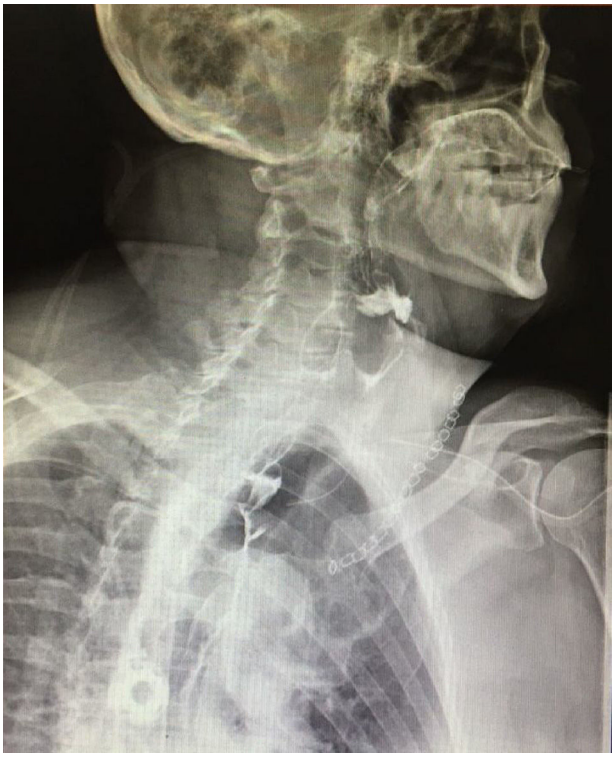

Figure 1 Post-esophagectomy contrast-enhanced swallow study in which no contrast material leakage from the esophageal lumen was observed.

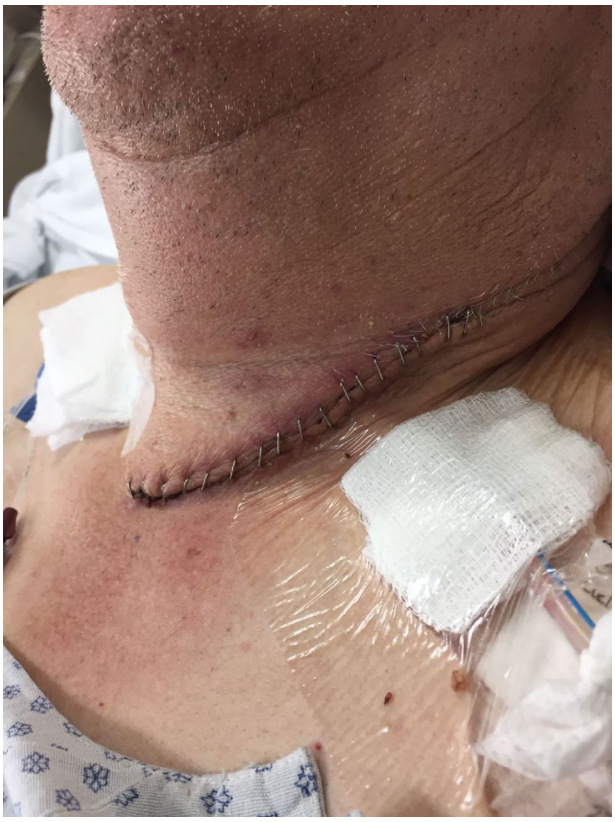

Figure 2 Clinical anastomotic leak, with the presence of surgical wound erythema and the drainage of saliva through a Jackson-Pratt drain, confirmed through amylase testing.

The indications for the procedure were divided into benign disease and malignant disease. Indication was for benign lesions in 29 patients (41.4%): 14 (20%) due to the ingestion of a caustic substance, 10 (14.3%) to perforation, 3 (4.3%) to achalasia, and 2 (2.9%) to Crohn's disease. It should be stressed that the achalasia cases underwent intervention after initial surgical treatment was unsuccessful and the three cases corresponded to ''sigmoid esophagus'' with emptying failure. Indication was for malignant neoplasia in 41 patients (58.6%): 30 (42.9%) due to adenocarcinoma, 8 (11.42%) to squamous cell carcinoma, and 3 (4.30%) to high-grade dysplasia.

Preoperative laboratory work-up results were a mean hemoglobin value of 13.97 mg/dl (9.3 to 18 mg/dl), with a median of 14 mg/dl, and a mean albumin value of 3.82 mg/dl (2.05 to 4.8 mg/dl), with a median of 3.9 mg/dl.

Of the 41 patients with malignant disease, 20 (48.80%) received neoadjuvant chemotherapy, 16 (39%) received neoadjuvant chemotherapy and radiotherapy, and 5 (12.20%) received no neoadjuvant therapy. Of the 5 patients that did not undergo neoadjuvant treatment, 3 presented with high-grade dysplasia, making said treatment unnecessary. The other 2 patients had clinical stage IIIA disease (T3N1M0) and due to the rapid advance of the tumors, surgical intervention was carried out with no neoadjuvant treatment.

Seventeen patients (41.5%) presented with clinical stage IIIA disease, 11 (26.8%) had clinical stage IIB, 5 (12.2%) had clinical stage IIIB, 3 (7.3%) had clinical stage IIIC, 1 (2.4%) had clinical stage IV, 1 (2.4%) had clinical stage IIA, and 3 patients (7.3%) had high-grade dysplasia.

The surgical approach was transhiatal in 64 (91.43%) of the study patients and transthoracic in 6 (8.57%). The stomach was used for continuity restoration in 59 cases (84.3%), and the colon was used in 11 (15.7%). Of those last 11 patients, the right colon was used in 4 (5.71%) and the left colon in 7 (10%). Mean surgery duration was 5.67 h, with a median of 5 h. Mean intraoperative blood loss was 523.72, with a median of 400 ml. Twenty-nine patients (41.43%) required intraoperative blood transfusion. Mean postoperative hemoglobin value was 11.83 mg/dl (6.2 to 16 mg/dl), with a median of 10.8 mg/dl. Seven patients (10%) presented with cardiovascular complications, 6 of whom had high blood pressure and one presented with acute myocardial infarction.

The immediate postoperative period was defined as the first two weeks after surgery and there was 87.14% morbidity (61 patients). The most frequent complications during that period were respiratory pathologies, which presented in 37 patients (52.86%): 14 patients (37.84%) had pleural effusion, 11 (29.73%) had pneumonia, 7 (18.92%) had atelectasis, and 5 (13.51%) had mediastinitis. Cervical anastomotic leak was in second place, with 30 patients (42.85%) and leak management was conservative in all the cases. Surgical wound infection was reported in 4 cases (5.71%). Recurrent dysphonia due to laryngeal nerve injury was described in 3 cases (4.28%) and those patients were referred to the Otorhinolaryngology service. Two patients (2.86%) presented with chylothorax, one of which required surgical intervention. Anastomotic stricture was found in 23 cases (32.86%), 14 of which had been operated on for benign lesions and 9 for malignant disease. Of the 23 patients with stricture, the stomach was used as a substitute in 21 of them and the colon in 2 patients. Stricture was resolved in the majority of those cases through endoscopy, except for two patients that had tumor recurrence and died. In those two cases, tumor recurrence was reported at 11 months and at 23 months, respectively. The mean number of dilations per patient was 12. At consultation, patients reported frequent chest pain and weight loss.

Mortality as a postoperative consequence was defined as death occurring within the first 30 days after the surgical procedure and was 4.28% (3 patients), due to infectious complications. Two of them died from mediastinitis complicated with septic shock and causes were malignant in all 3 cases. The 61 patients (87.14%) that presented with complications were divided according to the Clavien-Dindo classification: 3 patients (4.28%) with grade I, 22 patients (31.43%) with grade II, 22 patients (31.43%) with grade IIIa, 10 patients (14.28%) with grade IIIb, 1 patient (1.43%) with grade IVa, no patients with grade IVb, and 3 patients (4.28%) with grade V. The main procedures performed because of complications were intraoperative blood transfusions and dilations due to anastomotic stricture.

All 30 patients with anastomotic leak underwent contrast-enhanced swallow study at a mean 8.96 postoperative days (5-30 days), with a median of 7 days. However, the contrast-enhanced study was negative in 17 of those 30 patients, resulting in a sensitivity of 43.33% for the detection of leaks through the contrast-enhanced swallow study.

Discussion and conclusions

The contrast-enhanced swallow study is routinely performed after esophagectomy and before reinitiating oral diet in numerous hospitals worldwide.[5] Despite its advantages of low cost and relative safety, both limitations and complications associated with it have been reported. Among the limitations are prolonged stay in the intensive care unit and the use of an aqueous contrast medium, which has less radiographic density and less adherence to the mucosa. Its complication contrast medium aspiration with the consequent aspiration pneumonia or pulmonary edema.[4] That complication was not reported in our study.

A review article on gastrointestinal anastomotic leaks revealed a lack of consensus on the type of contrast medium used and when the study was carried out, which varied from 3 to 14 postoperative days.[5] Our study showed a median of 7 postoperative days for performing the contrast-enhanced swallow study.

We reported that 42.85% (n = 30) of our study patients presented with anastomotic leak after esophagectomy and that all of them (100%) underwent the contrast-enhanced swallow study. Said study detected the leak in only 17 patients, signifying sensitivity of 43.3%, a low and obsolete percentage for early leak detection. Consequently, the leaks in a high number of patients were not opportunely detected, increasing the risk for complications.

Other authors have described similar results. Boone et al. reported a 52% sensitivity for anastomotic leak detection through the contrast-enhanced swallow study, thus recommending its discontinuation as a routine study, but supporting its use when there is clinical suspicion of leakage, to evaluate its extension.[4] Likewise, Doerfer et al.[6] recommend its discontinuation as a routine study and suggest that it only be used in cases of clinical anastomotic leak or in cases of impaired gastrointestinal transit. They recommend the use of other imaging studies, reporting 100% sensitivity for tomography in relation to leak detection. Combining our results with those in the literature, given the low sensitivity of the contrast-enhanced swallow study, we recommend discontinuing its routine use, and in cases of clinical evidence of leakage (erythema, fever, or leakage of mucoserous matter from the wound and/or drain), performing computed tomography to evaluate the size of the fistula, rather than to make its diagnosis. Tomography is a much better method for assessing the size of the defect than using a water-soluble swallow. When carried out by an expert, endoscopy can be recommended for evaluating the fistula and for determining if the endoscopic therapeutic actions of clip, fibrin, or stent placement should be performed.[7]

Limitations of our study were its retrospective design and the fact that the clinical management of the leaks could have changed over time. In addition, our hospital performs only the contrast-enhanced swallow study as a diagnostic method for anastomotic leaks and therefore we could not our data with other imaging studies, such as endoscopy or tomography. Nevertheless, our results were comparable

with those of other studies.[4,7–10] Given the low sensitivity of the contrast-enhanced swallow study and the risk for aspiration with its use, other authors have also recommended its discontinuation.[11] However, of the radiologic studies, computed tomography with oral contrast medium can improve fistula detection, as well as determine its size.[12] Despite the time frame of our study, there have been no radical changes in the surgical approach to or treatment of anastomotic leaks at our hospital.

The *Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán* is an advanced speciality hospital in Mexico City, in which a large number of surgeries of the upper gastrointestinal tract are performed. Our specialists are well trained in the early detection of postoperative complications. These are all reasons why our data are also valid and useful for being applied to other Mexican hospitals.

In conclusion, our study demonstrated a discouraging rate of diagnostic accuracy upon finding a low sensitivity of 43.33% in relation to the contrast-enhanced swallow study. Therefore, we recommend the discontinuation of its routine use as a method for diagnosing anastomotic leaks. The clinical diagnosis of anastomotic leaks and the use of computed tomography to determine their size appear to be the best approach.

Ethical disclosures

Protection of human and animal subjects.

The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data.

The authors declare that no patient data appear in this article.

Right to privacy and informed consent.

The authors declare that no patient data appear in this article.

Financial disclosure

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Conflict of interest

The authors declare that there is no conflict of interest.

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